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Attorney Docket No. GENE-035/09US

PATENT

N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MENDRICK et al.

Confirmation No.: 1108

Serial No.:

09/917,800

Group Art Unit: 1631

Filed:

July 31, 2001

Examiner: M. I. Miller

For:

MOLECULAR TOXICOLOGY MODELING

U.S. Patent and Trademark Office Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08 for the above-identified patent application.

[]	In accordance wi	h 37 C.F.R.	§1.97(c),	also enclosed is:
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- [] the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
- a statement as specified in 37 C.F.R. §1.97(e).
- [X] A return receipt postcard is also enclosed.
- Please charge \$180.00 to Deposit Account No. 50-1283 for the total fee. This paper is being submitted in duplicate.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Respectfully submitted, COOLEY GODWARD LLP

Dated: February 27,2007

By:

(Hong Lin, Reg. # 54.891)

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Reg. No. 43,210

IN THE UNITED STATES PATENTAND RADEMARK OFFICE

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(c)

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- [X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- [X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- [X] The present application and its related applications generally disclose toxicology modeling of various tissues or cells, e.g., heart, kidney, liver, or primary hepatocytes using gene expression data. As such, some of the nucleic acid sequences disclosed in this application may overlap with those disclosed in other related applications. For the Examiner's convenience, a list of the co-pending applications is presented below.

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
09/917,800	Molecular Toxicology Modeling	July 31, 2001	Liver
10/501,933	Molecular Hepatoxicology Modeling	Jan. 31, 2003	Liver

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
11/059,535	Molecular Toxicology Modeling	Feb. 17, 2005	Liver
10/152,319	Molecular Toxicology Modeling	May 22, 2002	Kidney
10/515,325	Molecular Nephrotoxicology Modeling	Nov. 24, 2003	Kidney
11/036,196	Molecular Toxicology Modeling	Jan. 18, 2005	Kidney
11/642,647	Molecular Nephrotoxicology Modeling	Dec. 21, 2006	Kidney
10/338,044	Molecular Cardiotoxicology Modeling	Jan. 8, 2003	Heart
10/541,937	Molecular Cardiotoxicology Modeling	Jan. 8, 2004	Heart
11/600,759	Cardiotoxin Molecular Toxicology Modeling	Nov. 17, 2006	Heart
10/357,507	Primary Rat Hepatocyte Toxicology Modeling	Feb. 4, 2003	Hepatocyte
10/515,373	Primary Rat Hepatocyte Toxicity Modeling	Aug. 9, 2004	Hepatocyte
10/580,423	Methods For Molecular Toxicology Modeling	Nov. 24, 2004	General
11/547,759	Hepatotoxicity Molecular Models	Apr. 7, 2005	Liver

- [X] In particular, the following publications were cited by the U.S. Patent Examiner in U.S. application 09/917,800:
 - 1. U.S. 5,811,231
 - 2. U.S. 6,372,431
 - 3. U.S. 6,218,122
 - 4. Lashkari et al. PNAS, vol. 94: 13057-13062, 1997
- [X] The following publications were cited by the Examiner in U.S. application 10/152,319:
 - 1. "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at http://www.m-w.com/cgi-bin/dictionary?

 Book=Dictionary&va=nephrotoxic

- 2. Yamaki et al. Cellular mechanism of lithium-induced nephrogenic diabetes insipidus in rats. American Journey of Physiology Renal Physiology, 1991. Vol. 261, F505-F511
- [X]The following publication was cited by the Examiner in U.S. application 10/301,856:
 - 1. Konstandi et al. Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catechomaines, 2004 Chemico-Biological Interactions, vol. 147
- [X]The following publication was cited by the Examiner in U.S. application 10/191,803:

U.S. 6,461,807

- The following publications were cited by the Examiner in U.S. application [X] 10/357,507:
 - 1. U.S. 6,203,987
 - 2. Peng et al. JBC, 271(6):3324-3327
 - 3. GenBank Acc. No. AA799479 (4/30/1998)
 - 4. GenBank Acc. No. AI177366 (1/20/1999)
 - 5. GenBank Acc. No. M25823 (4/27/1993)
 - 6. GenBank Acc. No. AA891812 (1/25/1999)
- References were also cited in related or corresponding foreign [X]applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US01/23872.
 - 1. Raburn et al., "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," Endocrinology 136(12):5769 - 5777, 1995
 - 2. GenBank Accession No. L26268, Raburn et al., "Rattus norvegicus antiproliferative factor (BTG1) mRNA," January 26, 1996
 - 3. Bissig et al., "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol. Chem 269(4):3017-3021,
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 - 5. WO 00/12760

- 6. Farr et al., "Concise review: gene expression applied to toxicology," Toxicol Sci 50(1):1-9, 1999
- 7. Nuwaisyr et al., "Microarrays and toxicology: the advent of toxicogenomics," Molecular Carcinogenesis 24(3):153 - 159, 1999
- [X]References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US02/21735.
 - 1. US 2001/0039006 A1
 - 2. US 2002/0119462 A1
 - 3. Grigg et al. Environmental Health Institute to use gene chips to evaluate chemicals for potential harm to humans. NIEHS, 29 February 2000
 - 4. US 6,228,589
- [X] The following publications were cited in a foreign search or examination report corresponding to EP 01959321.9.
 - Markovich et al., "Heavy metals mercury, cadmium, and chromium 1. inhibit the activity if the mammalian liver and kidney sulfate transporter sat-1," Toxicol. Appl. Pharmacol. 154:181-187 (1999)
 - 2. WO 99/58670
 - 3. WO 93/01205
 - 4. WO 99/43345
 - 5. Berbner et al., "induction of cytochrome P450 IA and NDA damage in isolated rainbow trout (Onchorhynchus mykiss) hepatocytes by 2, 3, 7, 8tetrachlorodibenzo p-dioxin," Biomarkers 4: 214-228 (1999)
 - Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative 6. factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," Biochem. J. 336:471-481 (1998)
- The following publications were cited in a foreign search or examination [X]report corresponding to PCT/US03/03194:
 - 1. U.S. 6,218,122
 - 2. U.S. 2001/0049139

- [X] The following publications were cited in a foreign search or examination report corresponding to Canadian application 2,447,357
 - 1. WO 01/32928, 05/11/01, Far et al.
 - 2. Fielden *et al.* Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, Toxicol. Sci. 60: 6-10
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- [X] The following publications were cited in a foreign search or examination report corresponding to EP 02771863.4
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 - Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
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 - 6. Burchiel *et al.*, Analysis of genetic and epigentic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. Toxicol. Sci., 59: 193-195 (2001)
 - 7. WO 97/13877
 - 8. WO 01/25473
 - 9. WO 99/27090
- [X] The following publications were cited in a foreign search or examination report corresponding to PCT/US02/16173:
 - 1. U.S. 6,228,589
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 - 1. U.S. Publication 2002/0142284, 10/03/2002, Raha et al
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 - 3. WO 97/13877
- [X] The following publications were cited in a foreign search or examination report corresponding to EP 02806804.7
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- [X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/025646:

- 1. Wilson, et al. Exploring drug-induced alterations in gene expression in mycobacterium tuberculosis by microarray hybridization. 96:12833-12838 (1999)
- 2. Tao, et al., Profiling of differently expressed apoptosis-related genes by cDNA arrays in human cord blood DC34+ cells treated with etoposide. Experimental Hermatology, 31:251-2606 (2003)
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- 4. He et al., Histone deacetylase inhibitors induce remission in transgenic models of therapy-resistant acute promyelocytic leukemia., J. Biol. Chem., 276: 20858-20865 (2001)
- The following publications were cited in a foreign search or examination [X] report corresponding to PCT/US04/039593:
 - 1. U.S. Publication 2003/0124552, 07/03/2003, Lindemann et al
 - 2. U.S. 6,132,969, 02/17/2000, Stoughton et al.
 - 3. U.S. 2003/0154032, 08/14/2003, Pittman et al.
 - 4. U.S. 2003/0028327, 02/06/2003, Brunner et al.
 - 5. Hasegawa et al. Gan To Kagaku Ryoho 30: 325-33 (abstract)
- [X]The following publications were cited in a foreign search or examination report corresponding to PCT/US05/034780:
 - 1. Boorman et al., "Toxicogenomics, Drug Discovery, and the Pathologist," Toxicologic Pathology 30(1):15-27 (2002).
 - 2. Harris et al., "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," Mutation Research 539:79-99 (2004).
 - 3. Gooderham et al., "Molecular and genetic toxicology of 2-amino-1methyl-6-phenylimidazo[4,5-b]pyridine (PhIP)," Mutation Research 506-507:91-99 (2001).
 - 4. Hogstrand et al., "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," Comparative Biochemistry and Physiology Part B 133:523-535 (2002).

- [X]The following publications were cited in a foreign search or examination report corresponding to PCT/US05/011532:
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 - 3. Irizarry et al. Summaries of Affymetrix Gene Chip probe level data. Nucleic Acids Research, 2003, vol. 31, page e15
 - 4. U.S. 6,153,421
 - 5. U.S. 6,421,612
 - 6. U.S. 5,858,659

7. Jakubczak et al. An oncolytic adenovirus selective for retinoblastoma tumor suppressor protein pathway-defective tumors. Cancer Research, 2003 vol 63:1490-1499

This Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of:

[]	a final action under 37 C.F.R. §1.113;
	a notice of allowance under 37 C.F.R. §1.311; or
	an action that otherwise closes prosecution in this application.
In accordan	ce with 37 C.F.R. §1.97(c) also enclosed is:
	Fee under 37 C.F.R. §1.17(p) in the amount of \$180.00; or
[]	Statement as specified in 37 C.F.R. §1.97(e):
	[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

No item of information contained in the Information Disclosure Statement submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure

Attorney Docket No. GENE-035/09US

Serial No.: 09/917,800

Page 9

Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

Respectfully submitted, COOLEY GODWARD LLP

Dated: February 27, 2007

COOLEY GODWARD LLP

ATTN: Patent Group The Bowen Building

875 15th Street NW, Suite 800 Washington, DC 20005-2221

Tel: (202) 842-7800 Fax: (202) 842-7899 By:

(Hong Lia, Roy. # 54.891) Reg. No. 43,210

Approved for use through 07/31/2006. OMB 0651-0031

Sub	stitute for form 1449A/PTO	In AU	Complete if Known
		Application Number	09/917,800
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	07/31/01
		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	M. I. Miller
Sheet	1 of 24	Attorney Docket Number	GENE-035/09US

- 	U.S. PATENT DOCUMENTS				
		U.S. Patent Document	Name of Patentee or Applicant of	Date of Publication of Cited	
Examiner Initials*	Cite No.	Number Kind (if kn	Code Cited Document	Document MM-DD-YYYY	
	1.	5,811,231	Farr et al.	09-22-1998	
	2.	5,858,659	Sapolsky et al.	01-12-1999	
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	13.	2001/0039006	Snodgrass	11-8-2001	
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	16.	2002/0142284	Raha et al.	11-3-2002	
	17.	2003/0124552	Lindemann et al.	07-03-2003	
	18.	2003/0154032	Pittman et al.	08-14-2003	
	19.	2003/0028327	Brunner et al.	02-06-2003	

	FOREIGN PATENT DOCUMENTS						
Examiner	Cite	I I	oreign Patent D	ocument		1	Т
Initials*	No. ——	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Т
	20.	wo	93/01205		The Salk Institute for Biological Studies	1-21-1993	T
	21.	wo	94/17208		Xenometrix, Inc.	4-08-1994	\top
	22.	wo	97/13877		Lynx Therapeutics, Inc.	04-17-1997	\top
	23.	wo	99/27090		Smithkline Beecham Corporation	06-03-1999	
	24.	wo	99/43345		Eisai Co., Ltd.; Beth Israel Deaconess Medical Center	09-02-1999	
	25.	wo	99/58670		Cadus Pharmaceuticals Corporation	11-18-1999	
	26.	wo	00/12760		Incyte Pharmaceuticals	9-3-2000	T
	27.	wo	01/32928		Phase-1 Molecular Toxicology	05-10-2001	T
	28.	wo	01/25473		Source Precision Medicine, Inc.	04-12-2001	

Examiner	- ·	Date		<u>.</u>
Signature		Considered		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "Unique citation designation number (optional). "See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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29.

30.

Examiner

Initials*

Sub	stitute for form 1449A/PTO		Complete if Known		
		Application Number	09/917,800		
IN	FORMATION DISCLOSURE	Filing Date	07/31/01		
STATEMENT BY APPLICANT		First Named Inventor	MENDRICK		
~ -		Group Art Unit	1631		
	(use as many sheets as necessary)	Examiner Name	M. I. Miller		
Sheet	2 of 24	Attorney Docket Number	GENE-035/09US		

OTHER - NON PATENT LITERATURE DOCUMENTS

Aardema and MacGregor, Mutation Res., 499:13-25, (2002)

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book,

magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

"nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at

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	47.	Bajgar et al., Neurochem. Int., 24: 555-558 (1994)		
	46.	Atchison et al., Digestive Dis. Sci., 45: 614-620 (2000)		
	45.	Arano et al., Arzneim-Forsch./Drug, 46: 398-400 (1996)		
	44.	Anton et al., Cell Biochem. Biophys., 32: 27-36 (2000) Abstract only		
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	36.	Ala-Kokko, et al., Biochem. J., 244:75-79, (1987)		
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	32.	Affymetrix Rat Toxicology U34 Datasheet, released 08/99		
	31.	Adamson & Harman et al., Biochem. Pharmacol., 45: 2289-2294 (1993)		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Unique citation designation number (optional). See attached kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Sub	stitute for form 1449A/PTO		Complete if Known	
,		Application Number	09/917,800	
IN	FORMATION DISCLOSURE	Filing Date	07/31/01	
SI	STATEMENT BY APPLICANT	First Named Inventor	MENDRICK	
	Group Art Unit	1631		
	(use as many sheets as necessary)	Examiner Name	M. I. Miller	
Sheet	3 of 24	Attorney Docket Number	GENE-035/09US	-

		OTHER - NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	51.	Bartosiewicz et al., J. Pharmacol. Exp. Ther., 297: 895-905 (2001)
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	53.	Becker et al., Alzheimer Dis. Assoc. Disord., 10: 124-131 (1996)
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	61.	Birge et al., Toxicol. Appl. Pharmacol., 105: 472-482 (1990)
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	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	09/917,800	
IN	FORMATION DISCLOSURE	Filing Date	07/31/01	
ST	FATEMENT BY APPLICANT	First Named Inventor	MENDRICK	
		Group Art Unit	1631	_
	(use as many sheets as necessary)	Examiner Name	M. I. Miller	_
Sheet	4 of 24	Attorney Docket Number	GENE-035/09US	_

		OTHER - NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
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Sheat	5 of 24	Attornov Doolset Number	CENE 025/00HS	

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STATEMENT BY APPLICANT		Filing Date	07/31/01	_
		First Named Inventor	MENDRICK	_
		Group Art Unit	1631	
		Examiner Name	M. I. Miller	
Sheet	10 of 24	Attorney Docket Number	GENE-035/09US	

		OTHER - NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
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	(use as many sheets as necessary)	Examiner Name	M. I. Miller	
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Signature		Considered	

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	Application Number	09/917,800	
INFORMATION DISCLOSURE	Filing Date	07/21/01	

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STATEMENT BY APPLICANT

Application Number	09/917,800
Filing Date	07/31/01
First Named Inventor	MENDRICK
Group Art Unit	1631
Examiner Name	M. I. Miller
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		Application Number	09/917,800	
IN	FORMATION DISCLOSURE	Filing Date	07/31/01	·
STATEMENT BY APPLICANT		First Named Inventor	MENDRICK	
		Group Art Unit	1631	
(use as many sheets as necessary)		Examiner Name	M. I. Miller	
Sheet	17 of 24	Attornou Docket Number	CENE 035/00116	

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Substitute for form 1449A/PTO		Complete if Known		
		Application Number	09/917,800	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	07/31/01	
		First Named Inventor	MENDRICK	
		Group Art Unit	1631	
		Examiner Name	M. I. Miller	
Sheet	24 of 24	Attorney Docket Number	GENE-035/09US	

OTHER – NON PATENT LITERATURE DOCUMENTS				
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